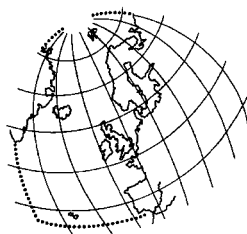


Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (New DYNAMEC Manual)



OSPAR Commission
2006

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the “OSPAR Convention”) was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. It has been ratified by Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, Netherlands, Norway, Portugal, Sweden, Switzerland and the United Kingdom and approved by the European Community and Spain.

La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. La Convention a été ratifiée par l'Allemagne, la Belgique, le Danemark, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède et la Suisse et approuvée par la Communauté européenne et l'Espagne.

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EXECUTIVE SUMMARY/ RÉCAPITULATIF

The Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC) was established, following the adoption at the OSPAR Ministerial Meeting in 1998 of the Hazardous Substances Strategy, as a tool to enable the OSPAR Commission to select those hazardous substances that need to be addressed under the Hazardous Substances Strategy and to identify the substances which should be given priority in OSPAR's work. The development and initial use of the DYNAMEC were recorded in the 2002 DYNAMEC document (publication number: 146-2002) which also drew together all the relevant procedures and criteria for the DYNAMEC work.

Le Mécanisme dynamique de sélection des substances dangereuses et de classement de celles-ci en fonction des priorités (mécanisme DYNAMEC) a été établi à la suite de l'adoption de Stratégie Substances Dangereuses à la réunion ministérielle d'OSPAR en 1998. Ce mécanisme constitue un outil qui permet à la Commission OSPAR de sélectionner les substances dangereuses devant être abordées dans le contexte de la Stratégie Substances Dangereuses et de déterminer les substances devant faire l'objet de mesures prioritaires dans le domaine des travaux d'OSPAR. L'élaboration et l'utilisation initiale du mécanisme DYNAMEC sont inscrites dans le document DYNAMEC publié en 2002 (numéro de publication : 146-2002), lequel rassemble toutes les procédures et tous les critères des travaux DYNAMEC.

Having concluded the initial selection and prioritisation work, OSPAR initiated in 2003 a study process on the selection and prioritisation of hazardous substances, in the light of similar work going on in the European Community (EC). This study process resulted in the conclusion in 2004 that OSPAR should not, for the time being, carry out a further systematic review of chemical substances in order to select and prioritise chemicals for priority action. In particular, there should, for the time being, be no re-run of DYNAMEC.

Ayant parachevé les travaux relatifs à la sélection initiale et au classement en fonction des priorités, OSPAR a, en 2003, lancé un processus d'étude portant sur la sélection et le classement des substances dangereuses en fonction des priorités, ceci à la lumière des travaux analogues dans le cadre de la communauté européenne (CE). Ce processus d'étude a conclu en 2004 qu'il n'y a pas lieu de procéder à un nouvel examen systématique des substances chimiques, afin de sélectionner des produits chimiques devant faire l'objet de mesures prioritaires, et de les classer en fonction des priorités. Notamment, pour l'instant, il n'y a pas lieu d'appliquer de nouveau le mécanisme DYNAMEC.

The conclusions were laid down in the Agreement for Further Work in relation to the DYNAMEC Mechanism, which replaces the Provisional Instruction Manual for the DYNAMEC Mechanism.

On trouvera les conclusions dans l'Accord sur la poursuite des travaux sur le mécanisme DYNAMEC, lequel remplace le Manuel d'instruction provisoire du mécanisme DYNAMEC.

This publication now draws together the current procedures and criteria developed in the framework of the dynamic selection and prioritisation mechanism for hazardous substances and serves as a manual for the application of the DYNAMEC. The 2002 DYNAMEC publication remains as a historic document recording the development and initial use of the mechanism.

Le présent rapport rassemble les procédures et critères actuels, élaborés dans le cadre du Mécanisme dynamique de sélection des substances dangereuses et de classement de celles-ci en fonction des priorités. Il constitue un guide de l'application du mécanisme DYNAMEC. La version du rapport DYNAMEC publiée en 2002 servira de document historique faisant état de l'élaboration et l'utilisation initiale du mécanisme.

1. INTRODUCTION

1.1 Purpose and development of DYNAMEC

1. The OSPAR Ministerial Meeting in 1998 agreed on the OSPAR Strategy with regard to Hazardous Substances¹ and declared in the Sintra Statement² that the OSPAR Commission would develop a dynamic selection and prioritisation mechanism (DYNAMEC) in order to tackle first the substances and groups of substances which cause most concern, and use this mechanism to up-date by 2000 the 1998 OSPAR List of Chemicals for Priority Action. The DYNAMEC is a tool to enable the OSPAR Commission to select those hazardous substances that need to be addressed under the Hazardous Substances Strategy and to identify the substances which should be given priority in OSPAR's work.
2. Following the update in 2000 of the OSPAR List of Chemicals for Priority Action³, work in 2000-2002 on the further development of DYNAMEC led to the establishment of the OSPAR List of Substances of Possible Concern⁴. The description of the DYNAMEC and the procedures for its application were published in 2002 in the Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC)⁵.
3. The OSPAR Commission adopted in 2003 revised Strategies of the OSPAR Commission for the Protection of the Marine Environment of the North-East Atlantic¹. The revised Hazardous Substances Strategy affirmed that the Commission will complete and maintain a dynamic selection and prioritisation mechanism to select the hazardous substances to be given priority in its work.

1.2 Further work in relation to the DYNAMEC

4. Having concluded the initial selection and prioritisation work, OSPAR initiated in 2003 a study process on the selection and prioritisation of hazardous substances, in the light of similar work going on in the European Community (EC). The aim was to address how to go forward with selection and prioritisation of hazardous substances in OSPAR, and to achieve an efficient collaboration of work between OSPAR and the EC on selection and prioritisation and provide options for action. Based on the outcome of the study process OSPAR 2004 concluded that OSPAR should not, for the time being, carry out a further systematic review of chemical substances in order to select and prioritise chemicals for priority action. In particular, there should, for the time being, be no re-run of DYNAMEC. OSPAR should retain the option to work on specific hazardous substances not covered within the EC framework which are assessed as being of concern for the marine environment.
5. To follow up the conclusions from the study process, OSPAR in 2005 revised the Provisional Instruction Manual for the DYNAMEC Mechanism which described the procedures on initial selection, ranking and prioritisation of substances, and also briefly the procedures for the further application of the DYNAMEC mechanism. The provisional instruction manual was replaced by the Agreement for Further Work in relation to the DYNAMEC Mechanism⁶. The OSPAR Commission also revised the agreement on cut-off-values for the DYNAMEC⁷. The deselection of substances from the List of Possible Concern the last years also meant that there was need to update the text accompanying the List of Substances of Possible Concern.

2. PROCEDURES AND CRITERIA FOR DYNAMEC

6. This publication compiles the updated procedures and criteria related to the dynamic selection and prioritisation mechanism for hazardous substances (DYNAMEC) and serves as a manual for the application of the DYNAMEC. The DYNAMEC publication from 2002 is kept as a historic document recording the development of the DYNAMEC and the initial use of it.

2.1 Organisation of the work

7. In order to carry out its work programme, HSC has re-constituted the Informal Group of DYNAMEC Experts (IGE) with the following terms of reference:

To review proposals for the exclusion of substances from the OSPAR List of Substances of Possible Concern and the inclusion in that list of substances proposed under the "safety net", in accordance with the procedures described in Annex 3.

2.2 The List of Substances of Possible Concern

8. The List of Substances of Substances of Possible Concern and the underlying fact sheets were published on the OSPAR website in order to promote active contributions to the process of initial selection, not only from Contracting Parties and observers of OSPAR but also from the general public. The text to accompany this List is at **Annex 2**, as revised to reflect the outcome of the study process and to update facts.

9. The fact sheets contain relevant and available information on identification of the substance, PBT characteristics, indication of which PBT information has been used for the initial selection, production volumes, use patterns, flags, remarks, and current rank. Confidential information is not set out in these fact sheets.

2.3 Procedures and criteria

10. **Annex 1** gives an overview of the steps and procedures within the DYNAMEC Mechanism. This has been adjusted since the first publication in 2002 to reflect the conclusions of the study process.

11. The Agreement for further work in relation to the DYNAMEC Mechanism is set out in **Annex 3**. The agreement focuses on the further processes on the selection of substances. The requirements for this are:

- (a) to consider new information on substances already on the List of Substances of Possible Concern;
- (b) to consider information on new substances not addressed under relevant EC initiatives and decide whether they should be added to the List of Substances of Possible Concern;
- (c) to consider information on substances proposed for addition to the List of Substances of Possible Concern via the Safety net procedure.

12. The revised agreement on Cut-Off Values for the Selection Criteria of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances is set out in **Annex 4**. Guidance with regard to temperature for degradation tests and on the use of sediment toxicity testing was incorporated in 2005.

13. **Annex 5** is the Guidance on How to Apply the Safety Net Procedure for the Inclusion of Substances in the List of Substances of Possible Concern⁸.

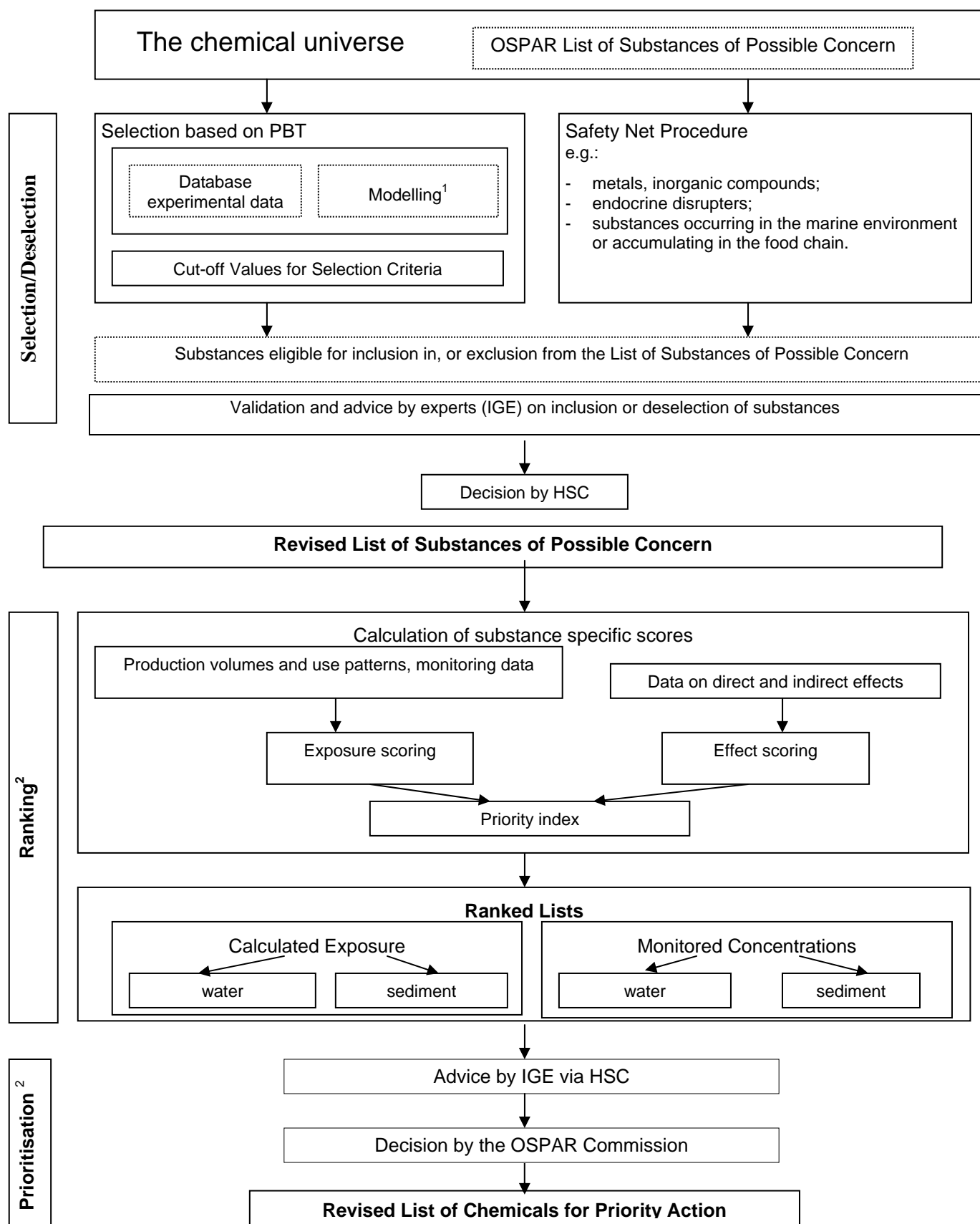
14. This manual will be updated when necessary.

REFERENCES

(indicated as endnotes in the text)

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- ¹ Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 34. The strategy was revised in 2003, Revised Strategies of the OSPAR Commission for the Protection of the Marine Environment of the North East Atlantic, Reference number 2003-21.
 - ² Sintra Statement. Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 45.
 - ³ The OSPAR List of Chemicals for Priority Action (reference number: 2004-12) has replaced the 1998 list which was published as Annex 2 to the 1998 OSPAR Strategy with regard to Hazardous Substances.
 - ⁴ The OSPAR List of Substances of Possible Concern (reference number: 2002-17) has replaced the 1998 OSPAR List of Candidate Substances (Annex 3 to the 1998 OSPAR Strategy with regard to Hazardous Substances).
 - ⁵ The Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC). Publication number: 146-2002
 - ⁶ The Provisional Instruction Manual for the DYNAMEC Mechanism (reference number: 2002-11) has been replaced by the Agreement for Further Work in relation to the DYNAMEC Mechanism (reference number: 2005-10).
 - ⁷ Cut-Off Values for the Selection Criteria of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances. Reference number: 2005-9 has replaced reference number: 2001-1.
 - ⁸ Guidance on How to Apply the Safety Net Procedure for the Inclusion of Substances in the List of Substances of Possible Concern. Reference number: 2002-10.

ANNEX 1: OVERVIEW OF THE STEPS AND PROCEDURES WITHIN THE DYNAMEC MECHANISM



1. Modelling results can not overrule good quality experimental data; however, new modelling results can overrule old modelling results if the latter are considered by experts to be less reliable
2. OSPAR will not, for the time being, take any new initiatives for prioritisation and ranking.

ANNEX 2: TEXT ACCOMPANYING THE "OSPAR LIST OF SUBSTANCES OF POSSIBLE CONCERN" AS PUBLISHED ON THE OSPAR WEB SITE

(Reference number: 2002-17) (2006 update)

Introduction

1. This web page is intended to inform visitors to the OSPAR web site about the OSPAR List of Substances of Possible Concern, and its role in OSPAR's efforts to tackle hazardous substances in the aquatic environment. The "question and answer" format is intended to give readers a quick overview of the list, the criteria used to develop it, and its robustness and status. A contact procedure is given for readers who could provide data and information to improve the list.

What is the status of the List of Substances of Possible Concern?

2. The OSPAR List of Substances of Possible Concern is a dynamic working list and will be regularly revised, as new information becomes available. This may lead to exclusion of substances present on the current version of the OSPAR List of Substances of Possible Concern and to inclusion of other substances if data on persistence, toxicity and liability to bioaccumulate (or evidence that they give rise to an equivalent level of concern) show that they should be added. This version of the OSPAR List of Substances of Possible Concern was last revised on dd.mm.yyyy.

Why has the List of Substances of Possible Concern been published?

3. The OSPAR Commission is publishing this List of Substances of Possible Concern in order to enable the transparency of its decisions on which substances to classify as chemicals for priority action, and to provide an opportunity for any errors or omissions in the data on which those decisions were based to be put right. Our goal is to keep this information up-to-date and accurate. If errors or omissions are brought to our attention, they will be corrected.

What is OSPAR doing to stop pollution by hazardous substances?

4. OSPAR's main objective for hazardous substances is to prevent pollution of the maritime area by continuously reducing their releases with the ultimate aim of achieving concentrations which are near background levels for those substances which occur naturally (e.g. lead, mercury) or close to zero for man-made substances. OSPAR has developed a strategy (the Strategy with regard to Hazardous Substances – *LINK*) to achieve this objective, and is making every endeavour to move towards the cessation by the year 2020 of discharges, emissions and losses of hazardous substances which could reach the marine environment.

How are relevant chemicals being identified and targeted?

5. In order to tackle the hazardous substances which are of possible concern to the marine environment, and to prioritise the substances of highest concern for immediate action, OSPAR has developed a selection and prioritisation mechanism. This is described in the publication on the Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC) as published on the OSPAR web site (publication no. 256/2006) [*LINK to DYNAMEC publication*].

How was the initial selection and prioritisation of these chemicals carried out, and how does the List of Substances of Possible Concern fit into this process?

6. The selection and prioritisation mechanism consisted initially of 3 basic steps:

step 1: an initial selection step which by a worst case screening procedure identifies certain hazardous substances on the basis of their intrinsic hazardous properties of persistence, liability to bioaccumulate and toxicity (P, B and T)¹. [*LINK to definitions of P, B and T in the glossary of the Strategy with regard to Hazardous Substances*] These have been placed on the List of Substances of Possible Concern" because they could adversely affect marine ecosystems;

¹ Cut-Off Values for the Selection Criteria of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances; Reference number: 2005-9

- step 2: a step which ranks these substances of possible concern according to their actual occurrence and effects in the marine environment;
- step 3: a step which selects those substances from the ranked list judged to require priority action by OSPAR. [[LINK to the current OSPAR List of Chemicals for Priority Action](#)]

Now that OSPAR has finalised the initial selection and prioritisation of substances, and taking account of progress within the European Community, what will OSPAR focus on in the future?

- 7. OSPAR 2004 agreed that the focus of the further processes on the selection of substances is:
 - (a) to consider new information on substances already on the List of Substances of Possible Concern;
 - (b) to consider information on new substances not addressed under relevant EC initiatives and decide whether they should be added to the List of Substances of Possible Concern;
 - (c) to consider information on substances proposed for addition to the List of Substances of Possible Concern via the Safety net procedure.

OSPAR will not, for the time being, take any new initiatives for prioritisation and ranking of substances. [[LINK to the Agreement for Further Work in relation to the DYNAMEC Mechanism \(Reference number: 2005-10\)](#)]

Are persistence, liability to bioaccumulate and toxicity the only criteria for selecting substances?

- 8. A number of substances which do not meet the full P, B and T criteria have already been added to the List of Substances of Possible Concern because it has been recognised that they give rise to a similar level of concern (for example, endocrine disruptors, or shown to be widely spread in the marine environment by monitoring). The procedures with which OSPAR may add further substances to the list on the basis of equivalent concern are presented in the Guidance on How to Apply the Safety Net Procedure for the Inclusion of Substances in the List of Substances of Possible Concern (reference number: 2002-10) .

How does the List of Chemicals for Priority Action relate to the List of Substances of Possible Concern?

- 9. The List of Substances of Possible Concern consists of the substances which have been selected on the basis of their intrinsic hazardous properties (step 1). The substances on the List of Chemicals for Priority Action are those which the OSPAR Commission has to date determined require priority action, based primarily on recommendations from DYNAMEC's ranking process and expert judgement as to which substances represent the highest concern due to the amount produced, the degree of hazardous properties and/or the actual occurrence in the marine environment (steps 2 and 3). As the work of OSPAR progresses, it is envisaged that the List of Chemicals for Priority Action will be further updated with substances from the List of Possible Concern in order that the objectives of the Strategy can be progressively met.

Where does the information about hazardous properties come from, and is it reliable?

- 10. The substances on the OSPAR List of Substances of Possible Concern have been identified by a worst case screening of a number of databases with experimental data on P, B and T. However, when experimental data are not available, substances have been identified by employing different models (QSARs: Quantitative Structure Activity Relationships) which estimate these values on the basis of chemical structure. The screening is not exhaustive as not all possible data sources have been available or because of limitations in the models employed. Furthermore, some substances may falsely have been selected due to data errors or outliers.

- 11. The P, B and T criteria used for the selection of the Substances of Possible Concern are described in Cut-Off Values for the Selection Criteria of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances. [[LINK to the cut-off values for the PBT criteria in Agreement number 2005-9](#)]

Is the underlying data used to select substances onto the List of Substances of Possible Concern available?

- 12. The underlying data used for the selection of the Substances of Possible Concern can be found on the relevant fact sheets.

Have the data on the List of Substances of Possible Concern been validated?

13. Expert judgement has been undertaken for only a part of the substances. Data for most of the substances have only been subjected to a preliminary scrutiny to ensure that they are sufficiently credible to indicate a possible concern. Therefore, there is still considerable room for improvement and confirmation of the data, that were used in a worst case screening procedure, especially if appropriate experimental values are available which may replace QSAR estimates. The extent to which the data for a certain substance has been scrutinised is indicated in the box "remarks" of the fact sheet for that substance.

What steps is OSPAR taking to improve the data?

14. OSPAR is keen to update the list and the fact sheets with more good quality data, and has been working with industry trade associations and OSPAR Contracting Parties to obtain such information. The more the list and the fact sheets become updated and validated with good quality data, the better the list will act as a tool to flag up those substances which are likely to be of concern to the marine environment.

What type of data would be of interest to OSPAR?

15. OSPAR is keen to get more good quality data with regard to the intrinsic properties (P,B and T) of these substances, or other substances with similar properties. However, OSPAR also does need information with regard to the production and use of these substances, and information on their occurrence in the environment.

What happens if new data comes forward on a substance which means that its selection is no longer justified?

16. Following expert review of additional data that has come forward, OSPAR has removed several substances from the list since it was first published. Information on these substances and the reasons for their removal can be found on the [List of Substances Removed from the OSPAR List of Substances of Possible Concern](#) (Reference number 2004-13). *[LINK to Substances removed from the OSPAR List of Substances of Possible Concern on the web page]*

17. The fact sheets for the deselected substances have been updated to include information about the reasons for deselection. Following this the fact sheets have been removed from the website and will not be updated any further. They are stored in the database of the OSPAR Secretariat and can be made available upon request to the Secretariat.

What can I do if I have information which might contribute to this process?

18. Visitors to this web site who have information which would enable OSPAR to update its List of Substances of Possible Concern are invited to contact the OSPAR Secretariat [[LINK to secretariat@ospar.org](mailto:secretariat@ospar.org)] who will advise them further regarding the submission of relevant information. An empty fact sheet for the submission of such information [[LINK to empty fact sheet on the web page](#)] and a glossary explaining the content of the fact sheet [[LINK to the glossary on the web page](#)] are available for downloading.

Disclaimer

19. The Commission accepts no responsibility or liability whatsoever with regard to the contents of the list or the supporting data sheets. Efforts have been made to ensure that the information given is as accurate as possible, but it is not necessarily comprehensive, complete, accurate or up-to-date.

20. This disclaimer is not intended to limit the liability of the Commission contrary to any obligations imposed by applicable national law nor to exclude liability for matters which may not be excluded under that law.

ANNEX 3: AGREEMENT FOR FURTHER WORK IN RELATION TO THE DYNAMEC MECHANISM

(Reference number: 2005-10)

Introduction

1. The OSPAR Hazardous Substances Strategy provided for the development of a dynamic selection and prioritisation mechanism to select the hazardous substances to be given priority in OSPAR work. The mechanism (the DYNAMEC mechanism) was developed and used for the initial selection and prioritisation of the OSPAR List of Chemicals for Priority Action. The Provisional Instruction Manual briefly described the procedures for the further application of the DYNAMEC mechanism.
2. Now that OSPAR has finalised the initial selection and prioritisation of substances, and taking account of progress within the European Community on work with the priority substances under the Water Framework Directive and the development of an EC Chemicals Strategy and a European Marine Strategy, OSPAR has agreed that it should only continue to address substances that raise concern for the marine environment when these are not addressed under the relevant EC initiatives.
3. This agreement therefore focuses on the further processes on the selection of substances. The requirements for this are:
 - (a) to consider new information on substances already on the List of Substances of Possible Concern;
 - (b) to consider information on new substances not addressed under relevant EC initiatives and decide whether they should be added to the List of Substances of Possible Concern;
 - (c) to consider information on substances proposed for addition to the List of Substances of Possible Concern via the safety net procedure.
4. The background for this agreement is that OSPAR will not, for the time being, take any new initiatives for prioritisation and ranking of substances.

A. POINTS OF DEPARTURE

5. In future, the main body of work on selection and prioritisation of hazardous substances should be carried out under the relevant EC initiatives².
6. OSPAR should not, for the time being, carry out a further systematic review of chemical substances in order to select and prioritise chemicals for priority action. In particular, there should, for the time being, be no re-run of DYNAMEC.
7. In principle, OSPAR should retain the option to work on specific hazardous substances not covered within the EC framework which are assessed as being of concern for the marine environment.
8. It is the task of HSC to maintain the DYNAMEC mechanism, and more specifically:
 - a. to maintain the List of Substances of Possible Concern, the ranked list(s) of substances of possible concern; and
 - b. to provide advice to the OSPAR Commission - on the Commission's specific request - on further substances to be selected for priority action.
9. It is furthermore the task of HSC to pursue generally the implementation of the OSPAR Hazardous Substances Strategy and to consider how the mix of OSPAR, EC and other initiatives are working together to deliver the objectives of that strategy within its timeframe. In this work, HSC and its subordinate bodies should ensure that:
 - a. they make the fullest possible use of material developed by the EC or other relevant international forums; and
 - b. they do not re-examine issues on which a conclusion has been reached in EC work, unless there is clear evidence that some aspect which is important for the marine environment has

² The relevant EC initiatives include the Combined Monitoring and Prioritisation System (COMMPS) procedure used for the purposes of the EC Water Framework Directive, the EC Existing Substances Regulation, the EC Interim PBT Strategy and the EC Registration, Evaluation and Authorisation of Chemicals (REACH) procedure for the purposes of the EC Chemicals Strategy, together with the EC Directives on cosmetics, pesticides, pharmaceuticals, veterinary medicines, and biocides.

been overlooked.

10. In principle, it is for the relevant industries (producers, formulators and downstream users) to provide reliable information on substances, to validate information and to produce draft fact sheets for hazardous substances. Furthermore, industry should guarantee public access to information on hazards and risks of substances and public participation in assessing and classifying substances. Since industry is gradually taking up these responsibilities, and actions for this purpose are being undertaken in other forums, it is not now appropriate for OSPAR to adopt any measures in this field.

11. Fact sheets for all substances on the List of Substances of Possible Concern are available on the OSPAR website. These contain all relevant and available information on identification of the substance, PBT³ characteristics, indication which PBT information has been used for the initial selection, production volumes, use patterns, remarks made by OSPAR and its subordinate bodies and its current ranking – that is, whether it has been prioritised for the purposes of the OSPAR Hazardous Substances Strategy. Confidential information is not presented on these fact sheets.

12. Furthermore, formats for the provision of additional information (including guidance setting out criteria e.g. for selecting substances under the Safety net procedure, reference number 2002-10) are available on the OSPAR website.

13. In order to carry out its work programme, HSC has re-constituted the Informal Group of DYNAMEC Experts (IGE) with the following terms of reference:

To review proposals for the exclusion of substances from the OSPAR List of Substances of Possible Concern and the inclusion in that list of substances proposed under the “safety net”, in accordance with the procedures described below.

14. Meetings of the IGE will be arranged as necessary. The aim will be to do this in conjunction with the preparation of the meetings of HSC. The procedures described below assume that this can be done. If a meeting of IGE at some other time is desirable, in order to avoid unreasonable delay in modifying the publicly available List of Substances of Possible Concern and the associated fact sheets under the procedures described below, the outcome of the work of the IGE may be endorsed by a written procedure of HSC.

B. SELECTION OF SUBSTANCES

I. Procedure for considering new information on substances already on the List of Substances of Possible Concern

15. Contracting Parties, observers (industry and other NGOs) and the general public can submit any relevant additional information on substances of possible concern. Amended or additional information should be submitted using the original fact sheet (to be downloaded from the OSPAR website) indicated with revision marks.

16. Amended fact sheets (including supporting information on original test reports or publications) should be sent in electronic form to the Secretariat not later than 8 weeks before the meeting of HSC.

17. The Secretariat should send them to the IGE not later than 7 weeks before the meeting of HSC.

18. The IGE should examine the comments made (mainly on the technical issues) and should prepare advice to HSC for consideration whether the provided information was of acceptable accuracy. Furthermore, the IGE should indicate any consequent adjustments to the List of Substances of Possible Concern (deselecting of a substance) or the List of Chemicals for Priority Action (prioritising a substance for action) and the reasons for such adjustments. The IGE should preferably work by e-mail correspondence but may meet in a face-to-face meeting.

19. The IGE should report on the outcome of its work to HSC. A report of the IGE should be sent to the Secretariat for submission to HSC not later than 3 weeks before the HSC meeting.

20. HSC should examine the advice of the IGE and decide on any adjustments on the information on the fact sheets and any adjustments on the List of Substances of Possible Concern.

21. In accordance with the agreements reached at HSC, the Secretariat should publish any revised fact sheets and the List of Substances of Possible Concern on the OSPAR website not later than 3 weeks after the HSC meeting. Any proposal for a change in the List of Chemicals for Priority Action should be referred to OSPAR for decision.

³ Persistence, liability to bioaccumulate and toxicity.

II. Procedure for selecting new substances of possible concern (using the intrinsic criteria in the initial selection/PBT)

22. There is general consensus that OSPAR would only be justified in selecting and prioritising further substances which are being introduced newly onto the market if those substances give rise to concern for the marine environment, and are not being addressed in the EC. Where such a justification is established, follow-up action should be organised case by case, using a lead-country approach.

23. Where:

- a. a substance is not being addressed under one of the EC initiatives; and
- b. a Contracting Party or observer has evidence suggesting that this substance raises concern for the marine environment, because either the PBT characteristics of the substance meet the agreed PBT criteria or the substances give rise to equivalent levels of concern,

that Contracting Party or observer should present that evidence to HSC and, on the basis of HSC advice, OSPAR should assess whether to select and prioritise that substance for priority action under the Hazardous Substances Strategy. The following procedure should be followed.

24. Contracting Parties and observers should present such evidence by submitting a filled-in fact sheet for any substance not yet on the List of Substances of Possible Concern, by using the format for fact sheets (to be downloaded from the OSPAR website).

25. Fact sheets (including supporting information of original test reports or publications) should be sent in electronic form to the Secretariat not later than 8 weeks before the HSC meeting.

26. The Secretariat should send them to the IGE not later than 7 weeks before the HSC meeting.

27. The IGE should examine the accuracy of the information on the fact sheets and should prepare advice to HSC for consideration whether the substances should, or should not be added to the List of Substances of Possible Concern. The IGE should preferably work by e-mail correspondence but could meet in a face-to-face meeting.

28. The IGE should report on the outcome of its work to HSC. A report of the IGE should be sent to the Secretariat for submission to HSC not later than 3 weeks before the HSC meeting.

29. HSC should examine the advice of the IGE and decide on the accuracy of the proposed fact sheets and any adjustments to be made to the List of Substances of Possible Concern.

30. In accordance with the agreements reached at HSC, the Secretariat should publish the fact sheets on the OSPAR website and adjust the List of Substances of Possible Concern not later than 3 weeks after the HSC meeting.

III. Procedure for selecting substances already on the market through the Safety net procedure

31. The same general approach as for new substances should be adopted for substances which are already on the market but which are believed to be of equivalent concern to substances meeting the PBT criteria, even though they do not meet all those criteria. The procedure for doing so is referred to as the Safety net procedure. The Guidance on How to Apply the Safety Net Procedure for the Inclusion of Substances in the List of Substances of Possible Concern is on the OSPAR website (reference number: 2002-10).

32. The detailed procedure should be parallel to that described in Section II.

C. RANKING OF SUBSTANCES

IV. Procedure for re-ranking the substances on the List of Substances of Possible Concern

33. There is general consensus that a re-run of DYNAMEC and re-ranking of the List of Substances of Possible Concern is not currently appropriate.

D. PRIORITISATION OF SUBSTANCES

V. Recommendations with respect to priority substances

34. OSPAR should not, for the time being, carry out a further systematic review of chemical substances in order to select and prioritise chemicals for priority action.

35. Nevertheless, any follow-up action under paragraph 22 may include consideration of prioritising the substance.

ANNEX 4: CUT-OFF VALUES FOR THE SELECTION CRITERIA OF THE OSPAR DYNAMIC SELECTION AND PRIORITISATION MECHANISM FOR HAZARDOUS SUBSTANCES

(Reference Number: 2005-9)

1. The intrinsic properties of individual substances, specifically whether they are persistent (P), toxic (T) or liable to bioaccumulate (B), determine whether they fall within the definition of hazardous substances given in the OSPAR Strategy with regard to Hazardous Substances. These three intrinsic properties (PTB criteria) have been used, along with cut-off values for each, as the criteria for selecting substances in the Initial Selection Procedure of the Dynamic Selection and Prioritisation Mechanism. The criteria are also used for selection of new substances (c.f. Agreement for Further Work in relation to the DYNAMEC Mechanism, reference number: 2005-8), as well as for deselecting substances. The cut-off values for each of these criteria are as follows:

Persistency (P): Half-life ($T_{1/2}$) of 50 days⁴ **and**

Liability to Bioaccumulate (B): $\log K_{ow} \geq 4$ or $BCF \geq 500$ **and**

Toxicity (T) T_{aq} : acute $L(E)C_{50} < 1$ mg/l, long-term $NOEC < 0,1$ mg/l

or

$T_{mammalian}$: CMR or chronic toxicity

2. This selection is a combination of the least stringent criteria considered during the development of the Initial Selection Procedure. For aquatic toxicity, contrary to the EC classification, mammalian toxicity is added in addition to the criteria for the aquatic environment (counts for all selections). For bioaccumulation the selected cut-off value is the same as that proposed for international harmonisation⁵ in classification and labelling. For persistence, the principal criterion is that the substance has a half-life in the freshwater or marine environment of 50 days or more. Further specification of the persistence criterion, including approaches applied in the absence of data on the half-life of a substance, are given in Appendix 1.

⁴ In the absence of data on half-lives, alternative approaches have been agreed, as described in Appendix 1, which allow the use of different types of available information on the biodegradability of a substance.

⁵ The process for and the results of the OECD Global Harmonisation of Classification Criteria can be found on the Internet at <http://www.oecd.org>

Appendix 1

Persistency Criteria within the Hazardous Substances Strategy

1. The persistence of a substance reflects the potential for the substance to reach the marine environment and to be transported to remote areas as well as the potential for long-term exposure of organisms. In order to assess the persistence in the marine environment in the context of the OSPAR Hazardous Substances Strategy an approach is applied that allows the use of different types of available information on the biodegradability of a substance. In this approach three different levels of information are defined:

- Level 3: Experimental data on persistence
- Level 2: Other experimental data
- Level 1: Data from biodegradation estimation models

2. An explanation of the type of information that is relevant within these levels and the relevant cut-off values is given below. It must be noted that this approach reflects existing knowledge on biodegradation and should be considered as a pragmatic approach that makes optimal use of the available data and methods. Clearly, more research is needed to better estimate persistence in the marine environment from existing biodegradation tests. Moreover, other degradation mechanisms such as hydrolysis and photolysis should be taken into account if they are relevant.

Level 3: Experimental data on persistence

3. The half-life should be used as the first and main criterion for determining whether substances should be regarded as persistent in the context of the Hazardous Substances Strategy. Hence appropriate half-life data override data from levels 1 and 2. In principle persistence should be determined in relevant simulation test systems that determine the half-life under relevant environmental conditions. The most relevant conditions should be considered; e.g. for a substance that could reach the marine environment only through transport by freshwater, the half-life in the freshwater environment is the most relevant, provided that the residence time in freshwater is sufficiently long. A cut-off value of 50 days should be used in freshwater (as a transport medium) as well as in the marine environment when it is likely that the substance can reach this compartment. As a general rule, in dealing with cases for deselection in which half-lives in freshwater or marine waters are considered, the degradation tests performed according to OECD protocols (or equivalent) under the most relevant environmental conditions are preferred for assessing against the 50 day cut-off value. Extrapolation of DT_{50} values to other conditions (e.g. temperature) will not be relied upon without justification, and tests performed under particular conditions need to be evaluated on a case by case basis.

4. The assessment of the half-life should include consideration of PBT-properties of metabolites. A substance is not considered to be a PBT substance if both of the following conditions are met: (i) the half-life of the parent compound is less than 50 days and (ii) the resulting metabolites are not PBT chemicals.

5. Half-life determination from experimental studies using a water-sediment system may be hampered by the formation of unextractable residues in the sediment, also called bound residues, that hardly exhibit further degradation (very slow formation of CO_2). Usually the nature of the bound residues cannot be clarified. If the bound residues would cause toxic effects, and correspond to a significant amount of the original parent substance, the parent substance (if it fulfils the B and T criterion) should be considered a PBT substance. A "significant amount" of bound residues could be any amount corresponding to more than 10% of the parent substance, but the assessment of what is a significant amount should be made on a case by case basis. Concerns over bound residues should be investigated through the use of sediment toxicity testing (using *Chironomus* or other appropriate sediment dwelling organisms) or by other types of tests that could show whether those residues are harmful to organisms. When such a test points out that the bound residues do not have toxic effects, the substance is considered to be non-PBT.

Level 2: Other experimental data

6. The available information relating to biodegradability is dominated by test results on Ready Biodegradability (OECD Test Guideline 301 a-d- or equivalent) and to a lesser extent by data on the Inherent Biodegradability (OECD TG 302 a-c or equivalent). The conditions for degradation in the freshwater and marine environment are very far from the conditions applied in these standard tests. Hence, extrapolation of the existing biodegradation information (either measured data from ready and inherent tests or results from QSAR modelling) to degradation rates in the marine environment is very difficult, and care should be taken not to over-interpret the outcome of the ready/inherent tests. However, in order to use the available

information to *select* potentially persistent substances the results of different types of tests should be used in the following way:

- when results from inherent tests are available that indicate that the substance does not fulfil the criteria this is a clear indication that the substance can reach the marine environment and be persistent under marine conditions, and that its initial selection is warranted.
- when only test results from ready biodegradation test are available indicating that the substance does not fulfil the criteria the substance is also initially selected. However, it is recognised that there is an urgent need for (industry to provide) better realistic data in order to determine the real potential for persistency. It must be noted that in this case it is not proposed that inherent tests are performed but rather to go directly to Level 3 testing.
- data from inherent tests that fulfil the pass criteria for these tests may still be persistent under marine conditions. However, in order to make the best use of available information it can be accepted that the results of two specific tests are used when they fulfil certain criteria. These tests are⁶:
 - Zahn-Wellens Test (OECD 302B): Pass level for ultimate degradation must be reached within 7 days, lag-phase should be no longer than 3 days, percentage removal in the test before degradation occurs should be below 15%, not tested with pre-adapted micro-organisms;
 - MITI II -test (OECD 302C): Pass level for ultimate degradation must be reached within 14 days, lag-phase should be no longer than 3 days, not tested with pre-adapted micro-organisms.

7. A case by case assessment is needed in order to decide that a substance can be deselected for persistency using the results from the above mentioned inherent tests.

Level 1: Data from biodegradation estimation models

8. For many chemicals no experimental data are available at all, which makes the initial selection of these substances problematic. Fortunately, models are available such as the SYRACUSE BIOWIN model that can be used to estimate the potential for biodegradation in the environment. It is proposed that rather stringent cut-off levels are used in order to select those substances for which there is a fair level of concern regarding their potential for persistence in the marine environment. A combination of two BIOWIN models has been used for the application of QSARs in the initial selection mechanism. The first model (BIOWIN 1) indicates that a substance is not rapidly degradable in the environment. The second model (BIOWIN 3) indicates that ultimate biodegradation in the environment is expected to occur in weeks to months where the exact cut-off point is "calibrated" on the basis of the data base for 1,2,4-trichlorobenzene, a substance that is known for being rather persistent under environmental conditions. In model terms the cut-off values are $BPP1 < 0,5$ and $BPP3 < 2,2$. It is recognised that further work in the development of biodegradation QSARs is needed and that experience with the cut-off values would be beneficial for future application of QSAR models within further work in relation to the DYNAMEC mechanism.

⁶ The criteria for the inherent tests are similar to the criteria defined in the EC Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, Chapter 3, Section 4, Environmental Risk Assessment – Marine.

ANNEX 5: GUIDANCE ON HOW TO APPLY THE SAFETY NET PROCEDURE FOR THE INCLUSION OF SUBSTANCES IN THE LIST OF SUBSTANCES OF POSSIBLE CONCERN

(Reference number: 2002-10)

Introduction

1. DYNAMEC 1999 had agreed to establish a Safety net procedure, in which expert judgement would be used to add substances to the List of Substances of Possible Concern. Arrangements for the submission of proposals for substances to be considered through this safety net procedure were made at DYNAMEC September 1999 and at DIFF 1999. The experience gained by Informal Group of DYNAMEC Experts (IGE) in reviewing these proposals indicated a need for agreed guidance to be taken into account:

- a. by Contracting Parties and observer organisations when making proposals for inclusion of substances on the List of Substances of Possible Concern;
- b. by experts when reviewing these proposals in the context of the application of the Safety net procedure with a view to improving clarity, transparency and consistency in their judgements.

Guidance

General aspects

2. In contrast to the clearly defined cut-off criteria for persistence, liability to bioaccumulate and toxicity (PBT)⁷ it is impossible to establish quantitative rules and criteria to be applied within the Safety net procedure. Proposals for addition of substances to the List of Substances of Possible Concern have to be reviewed on a case-by-case basis and the following criteria are intended only as qualitative guidance for experts.

3. It is the responsibility of the Contracting Party or observer organisation making a proposal for inclusion to supply the experts with the rationale for the proposal, supported by the necessary scientific and technical background data. Without such supporting data, the proposal should not be considered by the experts (inclusion of substances for policy reasons is outside the remit of the DYNAMEC mechanism).

Occurrence in the marine environment

4. Occurrence of a substance in the marine environment can be taken as a qualitative criterion in addition to the defined PBT criteria. This means that substances which do not meet all the criteria for persistence, bioaccumulation and toxicity (the PBT criteria) can be considered for inclusion in the List of Substances of Possible Concern, via the safety net procedure, provided that suitable monitoring data and associated information are provided which demonstrate the presence of the substance in the marine environment. Such information must be sufficiently extensive and reliable to enable experts (who will include experts on marine monitoring) to advise the OSPAR Commission that the substances give rise to a level of concern equivalent to that for, and require a similar approach as, substances which do meet all three sets of the PBT criteria.

5. Supporting information will therefore be needed on the location of sampling, the sampling and analytical methods used, quality assurance techniques applied and the suspected reasons for the findings which support inclusion of the substance in the list. Sampling should be recent, and should be sufficient to enable experts to satisfy themselves that the substance is present, or causing substance-specific effects in biota, on a scale causing reasonable concern from the point of view of the maritime area, or a recognisable sub-region, as a whole. In addition to direct evidence from sampling, the presence of a substance can be deduced if evidence shows that it is produced/imported in high volumes and released in widely dispersive uses that are likely to bring about inputs to the marine environment.

Metals

6. Because persistence and bioaccumulation cannot be used as criteria for metals, the question of whether a specific metal (inorganic compound) represents a possible concern for the marine environment has, in general, to be addressed by experts in the safety net procedure. Criteria that can be taken into account in this process include, *inter alia*:

- a. whether or not the metal is an essential element;

⁷ See Summary Record OSPAR 01/18/1, § 4.8 and Annex 6: Cut-Off Values for the Selection Criteria Used in the Initial Selection Procedure of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances.

- b. whether it is found in concentrations in the marine environment clearly exceeding natural background concentrations (taking into account the local/regional variations of these natural background levels);
- c. its speciation and the bioavailability of its various forms.

Substances with a high log Kow (>6)

7. Until such time as criteria on very persistent and very bioaccumulative substances are established, there is no guidance on substances with a high log Kow (>6).

Groups of substances

8. Recognising the definition of “group of substances” given in the OSPAR Strategy with regard to Hazardous Substances, single substances:

- a. having a structure similar to substances selected on the basis of PBT criteria and for which similar activity may be assumed; but
- b. which themselves would not be selected on the basis of the agreed PBT criteria;

should be reviewed to determine whether they may be treated together with the PBT-selected substance in the further selection process.

Endocrine disruptors

9. In view of:
- a. the requirements set out in the OSPAR Strategy with regard to Hazardous Substances as regards selection and prioritisation of endocrine disrupting chemicals;
 - b. the ongoing work within other international organisations as regards endocrine disruptors and the efforts underway to develop reliable tools and procedures to identify, select and prioritise endocrine disruptors;
 - c. the fact that 15 of the potential endocrine disruptors given in the lists 6 and 7 of Annex 3 of the OSPAR Strategy with regard to Hazardous Substances would not fulfil the PBT selection criteria;
 - d. the serious impacts that endocrine disrupting chemicals can have at very low concentrations and their potential wide-spread effects on populations, even if exposure is low, time-limited or affects only certain stages of an organism’s life cycle;

all potential endocrine disruptors given in lists 6 and 7 of Annex 3 of the OSPAR Strategy with regard to Hazardous Substances should automatically be included (and clearly flagged) in the list of substances of possible concern (see also §§ 4.5-4.7 in DYNAMEC 00/3/1⁸).

⁸ Extract of DYNAMEC 00/3/1:

§ 4.5 With regard to endocrine disruptors, the OSPAR Strategy indicates that the Commission will develop or adopt, as part of the selection mechanism, a means of identifying substances, which give reasonable grounds for concern that they are endocrine disruptors, and apply this means of identification to relevant substances. DYNAMEC 1998 also emphasised that the development of a routine identification and selection mechanism for endocrine disrupting substances was needed so that this could be incorporated in the OSPAR dynamic selection and prioritisation mechanism for hazardous substances.

§ 4.6 Various international forums currently contribute to the development of testing and assessment tools for identification and quantification of endocrine disruption. However, no internationally agreed criteria are available at present. As soon as those criteria become available, they should be incorporated in the criterion for toxicity.

§ 4.7 In expectation of the development of criteria for endocrine disruption, it is proposed to automatically select substances on the OSPAR List of Potential Endocrine Disruptors - parts A and B - as substances of possible concern for the marine environment and consequently subject these to the ranking algorithm. However, if a substance has been selected exclusively on the basis of possible endocrine disruption, this effect will be flagged.